UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,092	10/15/1999	JOACHIM HOFMANN	038311/0103	6828

31846 7590 11/20/2002

INTERVET INC
405 STATE STREET
PO BOX 318
MILLSBORO, DE 19966

EXAMINER
ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/20/2002

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/403,092	HOFMANN ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2002 and 08 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-26 and 29-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-26 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-26-2002 has been entered.

The amendments and responses filed on 4-26-2002 and 8-8-2002 are acknowledged. Claims 20, 23-25 and 30 have been amended. Claims 17-26 and 29-34 are pending and currently under examination.

Objections Maintained

Specification

The objection to the specification for the use of the various trademarks throughout this application is maintained for reasons of record. Applicant argues that a skilled artisan would understand what the trademarked material was and that providing generic terminology would needlessly increase the word count. Applicant's argument has been fully considered and deemed unpersuasive. Generic terminology is required to ensure that the skilled artisan would understand what said material was over the entire length of an issued patent.

Claim Objections

The objection to claim 30 based on the misspelling of *Dictyocaulus* ***viviparus*** is maintained for reasons of record. Said term is still misspelled.

New Claim Objections

Claim 24 objected to because of the following informalities: said claim recites two steps denoted as "b)" and no step denoted as "a)". Appropriate correction is required.

Claim Rejections Withdrawn

The rejection of claim 20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of the amendment thereto.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite by the use of the term "parts thereof" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 23 under 35 U.S.C. 112, first paragraph, based on the specification, while being enabling for an isolated nucleic acid which comprises SEQ ID NO:29, does not reasonably provide enablement for "a nucleic acid that hybridizes, under stringent conditions, to a nucleotide sequence according SEQ ID NO:29" is maintained for reasons of record.

Applicant argues:

1. The specification defines stringent conditions in the specification.

2. The defined hybridization conditions require that the fragments be of considerable length and homology to hybridize to the described sequences.

3. A skilled artisan would not interpret the limitations as meaning "a nucleic acid consisting of as few as two nucleotides.

Applicant's arguments have been fully considered and deemed non-persuasive. As outlined in the previous Office action, the rejected claim, as written, reads on **any** nucleic acid that hybridizes to a nucleic acid with the sequence of SEQ ID NO:29. This means that said claim, reads on nucleic acids consisting of as few as two nucleotides. Lathe (Journal of Molecular Biology, 1985, Vol. 183, No. 1, pp. 1-12) teaches a minimum probe length of 16-18 nucleotides for mammalian cDNA, and a probe length of 18-20 nucleotides for mammalian genomic DNA. These numbers are based on the estimated numbers of unique sequences in a cDNA library (-107) versus a genomic library (-109). Use of smaller oligonucleotides will result in non-specific hybridization, because the smaller oligonucleotide complementary sequence will no longer be unique. One of skill in the art would not know how to use oligonucleotides of less that 16 or 18 base pairs in length in carrying out a hybridization assay. **Additionally**, said claim would read on **all nucleic acids larger** in size than a nucleic acid with the sequence of SEQ ID NO:29, that would hybridize to a nucleic acid with a sequence of SEQ ID NO:29, including genomic DNA. Since the specification only describes the use of nucleic acids with the sequence of SEQ ID NO:29 and the specification provides no guidance for making said nucleic

acid in accordance with the claimed invention, said specification is only enabling for the nucleic acids with the sequence of SEQ ID NO:29.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., stringent conditions are defined as 6X SSC at 68 degrees C) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, there is no basis for Applicant's broad assertion that the aforementioned stringent conditions place any type of **requirement** on the sequence and homology of sequences to the described sequences.

Finally, contrary to Applicant's assertion, a skilled artisan would interpret the metes and bounds of the claimed to be as little as two nucleotides and include all **nucleic acids larger** in size than a nucleic acid with the sequence of SEQ ID NO:29.

The rejection of claims 24-25 under 35 U.S. C. 112, first paragraph, based on the specification, while being enabling for oligonucleotides which comprise SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO: 10; SEQ ID NO: 11; SEQ ID NO: 12; SEQ ID NO: 13; or SEQ ID NO: 14, does not reasonably provide enablement for "a part thereof" of the aforementioned oligonucleotides is maintained for reasons of record.

Applicant argues that Applicant have clearly contemplated and described the aforementioned "parts thereof" and hence have met their burden under 35 U.S.C. 112, first paragraph.

Applicant's arguments have been fully considered and deemed non-persuasive. As outlined in the previous Office action, said claims recite "parts thereof that hybridize with a sequence of the group under stringent conditions". Since said claims read on complementary nucleic acids, the limitation of "parts thereof that hybridize with a sequence of the group under stringent conditions" is not enabled by the specification. Said limitation reads on any nucleic acid that hybridizes to a nucleic acid with the sequence of SEQ ID N0:8-14. Said claims, therefore, reads on nucleic acids consisting of as few as two nucleotides. Lathe (Journal of Molecular Biology, 1985, Vol. 183, No. 1, pp. 1-12) teaches a minimum probe length of 16-18 nucleotides for mammalian cDNA, and a probe length of 18-20 nucleotides for mammalian genomic DNA. These numbers are based on the estimated numbers of unique sequences in a cDNA library (-107) versus a genomic library (-109). Use of smaller oligonucleotides will result in non-specific hybridization, because the smaller oligonucleotide complementary sequence will no longer be unique. One of skill in the art would not know how to use oligonucleotides of less that 16 or 18 base pairs in length in carrying out a hybridization assay. **Additionally**, said claim would read on **all nucleic acids larger** is size than a nucleic acid with the sequence of SEQ ID NO:8-14, that would hybridize to a nucleic acid with a sequence of SEQ ID NO:8-14, including genomic DNA. Since the specification only describes the use of nucleic acids with the sequence of SEQ ID NO:8-14 and the specification provides **no guidance** for making said nucleic acid in accordance with the scope of the claimed invention, said specification, contrary to Applicant's assertion, is only enabling for the nucleic acids with the sequence of SEQ ID NO:8-14.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 24-25 under 35 U.S.C. 112, second paragraph, as being indefinite by the use of the term "parts thereof is maintained for reasons of record.

Applicant argues that the term "parts thereof" is defined in the specification. Applicant arguments have been fully considered and are deemed non-persuasive for the reasons outlined above.

The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite by the use of the phrase "expressing the cDNA clone obtained according to claim 24" is maintained for reasons of record.

Applicant argues that the amendment to claim 24 overcomes said objection. Applicant's argument has been fully considered and is deemed non-persuasive. Since it is impossible to know what "clones" would be obtained according to claim 24 (see above), it is impossible to determine the metes and bounds of the claimed invention.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless —
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or m public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 17-20, 29-31 under 35 U.S. C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over de Leeuw et al. (Veterinary Parisitology Vol. 39 No. 1-2, 1991, pages 137-147, IDS-10) is maintained for reasons of record.

Applicant argues:

The Declaration by Mr. Cornelissen demonstrates that the claimed protein is different from that in the cited reference since the protein in the cited reference and a 18kD protein disclosed by Schneider react to the same antibody and the protein disclosed by Schneider has no relation to the protein of the instant invention since the sequences are different.

Applicant's arguments have been fully considered and are deemed to be non-persuasive. The Declaration by Mr. Cornelissen has been fully considered but is not found sufficient since his assertions are predicated on copies of gels. The copies of said gels provided the Office by fax transmission were of such poor quality that it is impossible to interpret them adequately. Hence, said Declaration fails to provide for the Examiner's evaluation any factual evidence to support the assertions made in said declaration. Applicant is again reminded that the sequence of the Schneider protein, upon which Applicant relies, has not been presented or made of record. Consequently, in the absence of the availability of supporting evidence to the contrary, the rejection over de Leeuw et al. is maintained.

The rejection of claims 17-26 and 29-34 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schnieder (International Journal of Parasitology, Vol. 22 No. 7, 1992, pages 933-938, IDS-10) is maintained for reasons of record.

Applicant argues:

The Declaration by Mr. Cornelissen demonstrates that the claimed protein is different from that in the cited reference since the protein in the cited reference and a 18kD protein disclosed by Schneider react to the same antibody and the protein disclosed by Schneider has no relation to the protein of the instant invention.

Applicant's arguments have been fully considered and are deemed to be non-persuasive. The Declaration by Mr. Cornelissen has been fully considered and has been found non-persuasive since it

fails to provide for the Examiner's evaluation any factual evidence to support the assertions made in said declaration (see above). Consequently, in the absence **of factual evidence** to the contrary, the protein disclosed by Schneider is deemed to be the same as that of the instant invention. The rejection over Schneider is maintained since the sequence data upon which Applicant relies have not been made available for evaluation.

It should be noted, that Applicant refers to declaration of Dr. Jan Cornelissen throughout his arguments. The Declaration provided by Applicant is by **Mr. Jan Cornelissen**, who is a laboratory technician with an education level commensurate with a Bachelor of Science (see Curriculum vitae attached to said declaration). Additionally, Mr. Cornelissen states he is a coauthor of a publication by de Cornelissen and de Leeuw. The cited reference does not have the authorship asserted by Mr. Cornelissen.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
November 12, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600